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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|----------------------|------------------|
| 10/706,544 | 11/12/2003 | Linda S. Powers | 13368.0001 (DIV. IV) | 6901 |

7590 08/23/2005
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/706,544

Applicant(s)

POWERS ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claim 1 is pending and under consideration.
2. Because this action raises a new ground of rejection, the action is made Non-Final.

Claim Objections

3. **(Prior Objection- Withdrawn)** Claim 1 was objected to because of the following informalities: a comma should be inserted between the terms “conjugated lipids” and “prion” in line 4 of the claim; and a comma should be inserted between the terms “prion” and “and microbial protein targets” in line 9 of the claim. In view of the amendments to the claims, the objection is withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **(New Rejection- Necessitated by Amendment)** Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim reads on a “method for capture of a biological analyte from a solution onto a substrate whereby the sample is passed over a substrate...” The claim is rejected for two reasons.

First, there is no antecedent basis in the claim for the term “the sample.” It is not clear what sample is being referred to.

Second, it is unclear if the “a substrate surface” referred to is a surface on the same, or on another, substrate as the one previously referred to in the claim. I.e., it is not clear how many substrates are involved in the claim.

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. **(Prior Rejection- Withdrawn)** Claim 1 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the claim was drawn to a method but did not set forth any steps involved in the method.

Claim 1 was also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

In view of the amendment of the claim to provide for a step to be performed in the method, the rejection is withdrawn.

8. **(Prior Rejection- Maintained)** Claim 1 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because subparts (e)-(k) of the claim each provide for an alternative intended use for the claimed method. It is unclear if the Applicant intended that the claimed method requires each of the different embodiments indicated by these subparts to the claim, or if the Applicant intended that these be alternative embodiments. The Applicant has cancelled subparts (g)-(k). Subparts (e) and (f) are each still presented. The Applicant asserts that the rejection is overcome by amending the subparts to refer to the claim preamble. However,

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each of (e) and (f) still appear to be alternative embodiments, although they are presented as part of the same claim without any indication that they are in fact in the alternative to each other.

Because the relationship of the two subparts is unclear, the rejection is maintained for the reasons of record.

It is suggested that these two subparts be cancelled from claim 1, and be incorporated into separate dependent claims.

9. **(Prior Rejection- Withdrawn)** Claim 1 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite as lacking antecedent basis for the phrase "the ligands used" in line 2 of the claim as previously presented. In view of the amendment of the claim to include antecedent basis for the term, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claim 1 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It was unclear whether the claims were limited to "non-antibody based ligands," or if the claims are intended to include such antibody based ligands as potential peptides specific for the outer membrane proteins. In view of the amendments and comments by the Applicant indicated that antibody, or antibody-derived sequences are excluded from the claims, the rejection is withdrawn.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. **(Prior Rejection- Maintained)** Claim 1 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for embodiments wherein the analyte to be detected is a prion, or embodiments wherein the substrate is used for the concentration of analytes from veterinary samples, an aerosol, food product slurries, food ingredient slurries, and soil slurries. The Applicant has cancelled the later embodiments from the claim. However, the Applicant traverses the rejection with respect to embodiments wherein the analyte to be detected is a prion, asserting that the application provides support for embodiments wherein the analyte is a protein, and that prions are known to be proteins, and that the application therefore provides support for the detection of prions. This argument is not found persuasive.

The genus of proteins encompasses a large number of different types of proteins. Applicant's argument amount to an argument that, by referring to proteins generally, the application provides support for any known protein or type of protein. However, disclosure of a genus of compounds is not adequate written description support for any particular species or subgenus within the disclosed genus. See e.g., *In re Welstead*, 174 U.S.P.Q. 449 (CCPA 1972). Because there is no disclosure in the present, or in the parent, applications for the currently claimed subgenus, the application provides insufficient support for embodiments wherein the analyte is a prion. The rejection is therefore maintained.

13. **(New Rejection)** Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. his claim is drawn to methods for the identification of a protein analyte comprising the use of a tethered ligand, wherein the tether is around 40 in length. However, while the present application discloses the use of tethers with a length of at least 40, the application discloses such tethers only for the use of ligands to whole microbial cells. Page 10, claim 1 (as submitted prior to the preliminary amendment). With respect to the ligands to peptides as used in the presently claimed method, the application discloses peptides of at least 6, but not the genus of tethers limited to those of at least 40 in length. The claim is therefore rejected as reading on new matter to the application.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. **(Prior Rejection- Maintained)** Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over PCT publication WO 98/49557, naming Powers et al. as inventors. The rejected claim reads on a method capturing a virus to a substrate surface with a ligand, wherein the ligand is specific to an outer membrane protein. The Applicant traverses the rejection on several grounds.

First, the Applicant asserts that Powers does not teach the asserted tether lengths that are to be used for each analyte to be captured. In particular, the Applicant appears to be arguing that

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the presently claimed tether length would not have been the obvious optimized length. However, the Applicant also states that the optimized tether length for the binding of protein substrates is about 6 μ m, not 40 μ m. Response, page 12. The Response argues that 40 μ m is a non-obvious optimized length for “intact microorganisms” (Id.); but, not for other macromolecules such as proteins (Page 13, stating “We have not observed any improvements in binding of macromolecules (unlike microorganisms) when the tether length exceeds 20 μ m.”). As the presently elected inventions are drawn to the binding of protein analytes, not intact microorganisms, the Applicant’s argument regarding the optimal binding of microorganisms does not appear relevant to the present claims. While the Applicant has shown complexity in determining the optimized length for analytes, there is no evidence that those in the art would not have used tethers of the prescribed lengths, or any indication that the use of such tethers would afford those in the art practicing the claimed invention any unanticipated results (e.g., unexpectedly good results). As the Applicant has provided no evidence sufficient to show a deficiency in the prima facie case, or any evidence of some other criteria of non-obviousness, the rejection is maintained.

Second, the Applicant asserts that Powers does not teach the steps of separating the substrate surface, or of washing away unbound portions of the sample. This second argument is not found persuasive as no such steps are included in the claim.

For these reasons, and for the reasons of record, the rejection is maintained.

2. **(Prior Rejection- Withdrawn)** Claim 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over Klempner et al. (U.S. Patent Application Publication U.S. 2002/0187464. The

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rejected claims read on a method for capture of a virus to a substrate using a peptide ligand specific to outer membrane proteins thereof. In view of Applicant's amendment to the claims, and arguments in support of such, indicating that the claims exclude the use of antibody or antibody-derived ligands (see , Response, page 14), the rejection is withdrawn.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. **(Prior Rejection- Maintained)** Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 21, 23, and 27 of U.S. Patent No. 6,780,602. The Applicant traverses this rejection on the basis that the "patentably distinctness of claim 1 of the present application from claims in U.S. Patent 6,780,602 was confirmed by final rejection by the ...[USPTO] of subsequent applications to link the claims, in which applicant claimed that the instant claim 1 traversed on the ground that the species were not patentably distinct." It is not clear what the Applicant is arguing. However, Applicant appears to be asserting that the rejection is improper as the Office has previously enforced a restriction requirement between the pending claim 1 and the patented claims. It is

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noted that upon allowance of the prior claims, the restriction requirement was withdrawn from claims that read on overlapping subject matter with the present claims. Thus, the present claim is not protected from double patenting as the restriction requirement was withdrawn. The rejection is therefore maintained.

17. **(Prior Rejection- Maintained)** Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 8 of copending Application No. 10/706,542. No arguments in traversal of this provisional rejection have been provided. The rejection is therefore maintained.

18. **(Prior Rejection- Restated and Maintained)** Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21 copending Application No. 10/706,542. It is noted that the rejection was intended to be over the indicated claim of Application 10/706,547. No arguments in traversal of this provisional rejection have been provided. The rejection is therefore maintained.

Conclusion

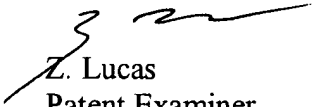
19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

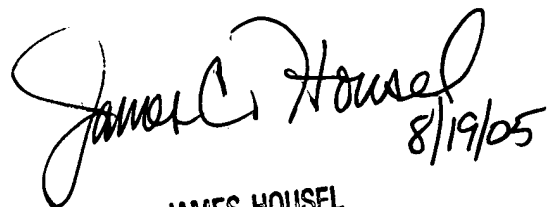
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



8/19/05
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